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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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	:
LEON FILEDS,	:
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	:
Plaintiff,	:
	:
-against-	:
	:
MERCK & CO., INC.,	:
	:
Defendant.	:
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No.: 07 cv 8387 (DLC)

**ANSWER AND JURY DEMAND
OF DEFENDANT MERCK &
CO., INC.**

Defendant Merck & Co., Inc. ("Merck") answers the Complaint ("Complaint")
herein as follows:

RESPONSE TO "JURISDICTION"

1. The allegations contained in paragraph 1 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required Merck denies each and every allegation contained in paragraph 1 of the Complaint except admits that there is diversity between the parties and that Plaintiff purports to put more than \$75,000 in controversy.

RESPONSE TO "PARTY PLAINTIFFS"

2. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 2 of the Complaint, except admits, upon information and belief, that Leon Fileds is a resident of the State of New York.

RESPONSE TO "PARTY DEFENDANT"

3. Admits that Merck is a New Jersey Corporation with its principal place of business in New Jersey.

4. Denies each and every allegation contained in paragraph 4 of the Complaint except admits that Merck is authorized to do business in the State of New York.

5. Denies each and every allegation contained in paragraph 5 of the Complaint except admits that Merck is authorized to do business in the State of New York.

6. Denies each and every allegation contained in paragraph 6 of the Complaint except admits that Merck is authorized to do business in the State of New York.

7. Denies each and every allegation contained in paragraph 7 of the Complaint except admits that Merck is authorized to do business in the State of New York.

8. Denies each and every allegation contained in paragraph 8 of the Complaint except admits that Merck is authorized to do business in the State of New York.

9. Denies each and every allegation contained in paragraph 9 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

RESPONSE TO “FACTUAL BACKGROUND”

10. Denies each and every allegation contained in paragraph 10 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

11. Denies each and every allegation contained in paragraph 11 of the Complaint except admits that Vioxx is the brand name for rofecoxib and that Vioxx reduces pain and inflammation and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2).

12. Denies each and every allegation contained in paragraph 12 of the Complaint except admits that Vioxx reduces pain and inflammation and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2)

13. Denies each and every allegation in paragraph 13 of the Complaint except admits that Merck submitted a New Drug Application for Vioxx on November 23, 1998 and respectfully refers the Court to the referenced New Drug Application for its actual language and full text.

14. Denies each and every allegation in paragraph 14 of the Complaint except admits that Merck submitted a New Drug Application for Vioxx on November 23, 1998 and respectfully refers the Court to the referenced New Drug Application for its actual language and full text.

15. Denies each and every allegation contained in paragraph 15 of the Complaint except admits that in May 1999 Merck received FDA approval to manufacture and

market the prescription medicine Vioxx subject to the information contained in the FDA-approved prescribing information and respectfully refers the Court to the relevant prescribing information for its actual language and full text.

16. Denies each and every allegation set forth in paragraph 16 of the Complaint and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its actual language and full text.

17. Denies each and every allegation contained in paragraph 17 of the Complaint and avers that in March 2000 Merck forwarded to the FDA the Vioxx Gastrointestinal Outcomes Research (VIGOR) study and subsequently, in June 2000, filed a supplemental New Drug Application (sNDA) that included the VIGOR study. Merck respectfully refers the Court to the referenced sNDA for its actual language and full text.

18. Denies each and every allegation in paragraph 18 of the Complaint except admits that the VIGOR study exists and respectfully refers the Court to that study for its actual language and full text.

19. Denies each and every allegation contained in paragraph 19 of the Complaint except admits that the studies referenced in the first sentence of paragraph 19 and the article referenced in the second sentence of paragraph 19 exist, and respectfully refers the Court to said publications for their actual language and full text. Merck further admits that it is currently a member of the European League Against Rheumatism (“EULAR”) and that it has been a sponsor of EULAR since 1999.

20. Denies each and every allegation contained in paragraph 20 of the Complaint.

21. Denies each and every allegation contained in paragraph 21 of the Complaint except admits that the referenced publication exists and respectfully refers the Court to said publication for its actual language and full text.

22. Denies each and every allegation contained in paragraph 22 of the Complaint except admits the existence of the journal and the article contained therein and respectfully refers the Court to the referenced article for its actual language and full text.

23. Denies each and every allegation contained in paragraph 23 of the Complaint except admits the referenced articles and study exist and respectfully refers the Court to the referenced articles and study for their actual language and full text.

24. Denies each and every allegation in paragraph 24 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

25. Denies each and every allegation in paragraph 25 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

26. Denies each and every allegation in paragraph 26 of the Complaint except admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

27. Denies each and every allegation contained in paragraph 27 of the Complaint except admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the prescribing information for Vioxx for its actual language and full text and admits that the FDA approved a so-

called “Dear Doctor” letter and respectfully refers the Court to the letter for its actual language and full text.

28. Denies each and every allegation in paragraph 28 of the Complaint except Merck admits that in April 2002 the FDA approved certain changes to the Vioxx prescribing information and respectfully refers the Court to the prescribing information for Vioxx for its actual language and full text.

29. Denies each and every allegation contained in paragraph 29 of the Complaint except admits that the FDA approved a so-called “Dear Doctor” letter and respectfully refers the Court to the letter for its actual language and full text.

30. Denies each and every allegation contained in paragraph 30 of the Complaint.

31. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 31 of the Complaint.

32. Denies each and every allegation contained in paragraph 32 of the Complaint.

33. Denies each and every allegation contained in paragraph 33 of the Complaint except admits that Plaintiff purports to quote from one of Merck’s Annual Reports and respectfully refers the Court to said Annual Report for its actual language and full text.

34. Denies each and every allegation contained in paragraph 34 of the Complaint except admits that Plaintiff purports to quote from one of Merck’s SEC filings and respectfully refers the Court to said filing for its actual language and full text.

35. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 35 of the Complaint.

36. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 36 of the Complaint.

37. Denies each and every allegation contained in paragraph 37 of the Complaint.

**RESPONSE TO “FIRST CAUSE OF ACTION
(Strict Products Liability)”**

38. With respect to the allegations contained in paragraph 38 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 37 of this Answer with the same force and effect as though set forth here in full.

39. Denies each and every allegation contained in paragraph 39 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

40. Denies each and every allegation contained in paragraph 40 of the Complaint.

41. Denies each and every allegation contained in paragraph 41 of the Complaint.

42. Denies each and every allegation contained in paragraph 42 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

43. Denies each and every allegation contained in paragraph 43 of the Complaint.

44. Denies each and every allegation contained in paragraph 44 of the Complaint.

45. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 45 of the Complaint and in the alternative denies same.

46. Denies each and every allegation contained in paragraph 46 of the Complaint.

47. Denies each and every allegation contained in paragraph 47 of the Complaint.

48. Denies each and every allegation contained in paragraph 48 of the Complaint.

49. Denies each and every allegation contained in paragraph 49 of the Complaint.

**RESPONSE TO “SECOND CAUSE OF ACTION
(Negligence and Negligence Per Se)”**

50. With respect to the allegations contained in paragraph 50 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 49 of this Answer with the same force and effect as though set forth here in full.

51. Denies each and every allegation contained in paragraph 51, including subparagraphs (a) through (i), of the Complaint.

52. Denies each and every allegation contained in paragraph 52 of the Complaint.

53. Denies each and every allegation contained in paragraph 53 of the Complaint.

54. Denies each and every allegation contained in paragraph 54 of the Complaint.

**RESPONSE TO “THIRD CAUSE OF ACTION
(Breach of Express Warranty)”**

55. With respect to the allegations contained in paragraph 55 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 54 of this Answer with the same force and effect as though set forth here in full.

56. Denies each and every allegation contained in paragraph 56 of the Complaint.

57. Denies each and every allegation contained in paragraph 57 of the Complaint.

58. Denies each and every allegation contained in paragraph 58 of the Complaint.

59. Denies each and every allegation contained in paragraph 59 of the Complaint.

60. Denies each and every allegation contained in paragraph 60 of the Complaint.

61. Denies each and every allegation contained in paragraph 61 of the Complaint.

**RESPONSE TO “FOURTH CAUSE OF ACTION
(Breach of Implied Warranty)”**

62. With respect to the allegations contained in paragraph 62 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 61 of this Answer with the same force and effect as though set forth here in full.

63. Denies each and every allegation contained in paragraph 63 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

64. The allegations contained in paragraph 64 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

65. Denies each and every allegation contained in paragraph 65 of the Complaint.

66. Denies each and every allegation contained in paragraph 66 of the Complaint.

67. Denies each and every allegation contained in paragraph 67 of the Complaint.

68. Denies each and every allegation contained in paragraph 68 of the Complaint.

69. Denies each and every allegation contained in paragraph 69 of the Complaint.

**RESPONSE TO “FIFTH CAUSE OF ACTION
(Fraudulent Misrepresentation)”**

70. With respect to the allegations contained in paragraph 70 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 69 of this Answer with the same force and effect as though set forth here in full.

71. Denies each and every allegation contained in paragraph 71 of the Complaint.

72. Denies each and every allegation contained in paragraph 72 of the Complaint.

- 73. Denies each and every allegation contained in paragraph 73 of the Complaint.
- 74. Denies each and every allegation contained in paragraph 74 of the Complaint.
- 75. Denies each and every allegation contained in paragraph 75 of the Complaint.
- 76. Denies each and every allegation contained in paragraph 76 of the Complaint.
- 77. Denies each and every allegation contained in paragraph 77 of the Complaint.
- 78. Denies each and every allegation contained in paragraph 78 of the Complaint.
- 79. Denies each and every allegation contained in paragraph 79 of the Complaint.
- 80. Denies each and every allegation contained in paragraph 80 of the Complaint.
- 81. Denies each and every allegation contained in paragraph 81 of the Complaint.
- 82. Denies each and every allegation contained in paragraph 82 of the Complaint.

**RESPONSE TO “SIXTH CAUSE OF ACTION
(Fraudulent Concealment)”**

83. With respect to the allegations contained in paragraph 83 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 82 of this Answer with the same force and effect as though set forth here in full.

- 84. Denies each and every allegation contained in paragraph 84 of the Complaint.
- 85. Denies each and every allegation contained in paragraph 85 of the Complaint.
- 86. Denies each and every allegation contained in paragraph 86, including subparagraphs (a) through (o), of the Complaint.

87. The allegations contained in paragraph 87 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

- 88. Denies each and every allegation contained in paragraph 88 of the Complaint.

- 89. Denies each and every allegation contained in paragraph 89 of the Complaint.
- 90. Denies each and every allegation contained in paragraph 90 of the Complaint.
- 91. Denies each and every allegation contained in paragraph 91 of the Complaint.
- 92. Denies each and every allegation contained in paragraph 92 of the Complaint.
- 93. Denies each and every allegation contained in paragraph 93 of the Complaint.
- 94. Denies each and every allegation contained in paragraph 94 of the Complaint.

**RESPONSE TO “SEVENTH CAUSE OF ACTION
(Negligent Misrepresentation)”**

95. With respect to the allegations contained in paragraph 95 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 94 of this Answer with the same force and effect as though set forth here in full.

96. The allegations contained in paragraph 96 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

- 97. Denies each and every allegation contained in paragraph 97 of the Complaint.
- 98. Denies each and every allegation contained in paragraph 98 of the Complaint.
- 99. Denies each and every allegation contained in paragraph 99 of the Complaint.
- 100. Denies each and every allegation contained in paragraph 100 of the Complaint.
- 101. Denies each and every allegation contained in paragraph 101 of the Complaint.
- 102. Denies each and every allegation contained in paragraph 102 of the Complaint.
- 103. Denies each and every allegation contained in paragraph 103 of the Complaint.

**RESPONSE TO "EIGHTH CAUSE OF ACTION
(Fraud and Deceit)"**

104. With respect to the allegations contained in paragraph 104 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 103 of this Answer with the same force and effect as though set forth here in full.

105. Denies each and every allegation contained in paragraph 105 of the Complaint except admits that Merck scientists have participated in studies involving Vioxx.

106. Denies each and every allegation contained in paragraph 106 of the Complaint.

107. Denies each and every allegation contained in paragraph 107 of the Complaint.

108. The allegations contained in paragraph 108 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

109. Denies each and every allegation contained in paragraph 109 of the Complaint.

110. Denies each and every allegation contained in paragraph 110 of the Complaint.

111. Denies each and every allegation contained in paragraph 111 of the Complaint.

112. Denies each and every allegation contained in paragraph 112 of the Complaint.

113. Denies each and every allegation contained in paragraph 113 of the Complaint.

114. Denies each and every allegation contained in paragraph 114 of the Complaint.

115. Denies each and every allegation contained in paragraph 115 of the Complaint.

116. Denies each and every allegation contained in paragraph 116 of the Complaint.

117. Denies each and every allegation contained in paragraph 117 of the Complaint.

118. Denies each and every allegation contained in paragraph 118 of the Complaint.

119. Denies each and every allegation contained in paragraph 119 of the Complaint.

120. Denies each and every allegation contained in paragraph 120 of the Complaint.
121. Denies each and every allegation contained in paragraph 121 of the Complaint.
122. Denies each and every allegation contained in paragraph 122 of the Complaint.
123. Denies each and every allegation contained in paragraph 123 of the Complaint.
124. Denies each and every allegation contained in paragraph 124 of the Complaint.
125. Denies each and every allegation contained in paragraph 125 of the Complaint.
126. Denies each and every allegation contained in paragraph 126 of the Complaint
except admits that Merck marketed the prescription medicine Vioxx.

127. Denies each and every allegation contained in paragraph 127 of the Complaint.
128. Denies each and every allegation contained in paragraph 128 of the Complaint.
129. Denies each and every allegation contained in paragraph 129 of the Complaint.
130. Denies each and every allegation contained in paragraph 130 of the Complaint.
131. Denies each and every allegation contained in paragraph 131 of the Complaint.
132. Denies each and every allegation contained in paragraph 132 of the Complaint.
133. Denies each and every allegation contained in paragraph 133 of the Complaint.

RESPONSE TO "PRAYER FOR RELIEF"

134. Plaintiff's "Prayer For Relief" section of the Complaint is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation in the "Prayer For Relief" section of Plaintiff's Complaint and denies that Plaintiff is entitled to the relief requested.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

135. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and statutes of repose and is otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

136. The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

137. The claims of the Plaintiff may be barred, in whole or in part, from recovery because they have made statements or taken actions that preclude them from asserting claims or constitute a waiver of their claims.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

138. The claims of the Plaintiff may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

139. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

140. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were cause in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A SEVENTH
DEFENSE, MERCK ALLEGES:**

141. To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

142. To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

143. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A TENTH
DEFENSE, MERCK ALLEGES:**

144. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

145. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Vioxx.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

146. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

147. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

148. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

149. Plaintiff's claims of fraud are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

150. Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

151. Plaintiff's claims are barred in whole or in part by the First Amendment.

**AS FOR A EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

152. Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**AS FOR A NINETEENTH
DEFENSE, MERCK ALLEGES:**

153. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

154. This case is more appropriately brought in a different venue.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

155. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, they have brought actions and have received judgments on parts of some or all claims asserted herein.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

156. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

157. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to their claims.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

158. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

159. The claims of Plaintiff are barred, in whole or in part, by their failure to mitigate damages.

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

160. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

161. The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

162. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES:**

163. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

164. Plaintiff has not sustained any injury or damages compensable at law.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

165. To the extent that Plaintiff seeks exemplary or punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

166. To the extent that Plaintiff seeks exemplary or punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of exemplary or punitive damages is barred.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

167. Plaintiff's demand for exemplary or punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

168. Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

169. Plaintiff's claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

170. Plaintiff's claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

171. Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

172. Plaintiff's claims are barred by the doctrine of contributory negligence.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
October 8, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

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Theodore V. H. Mayer
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